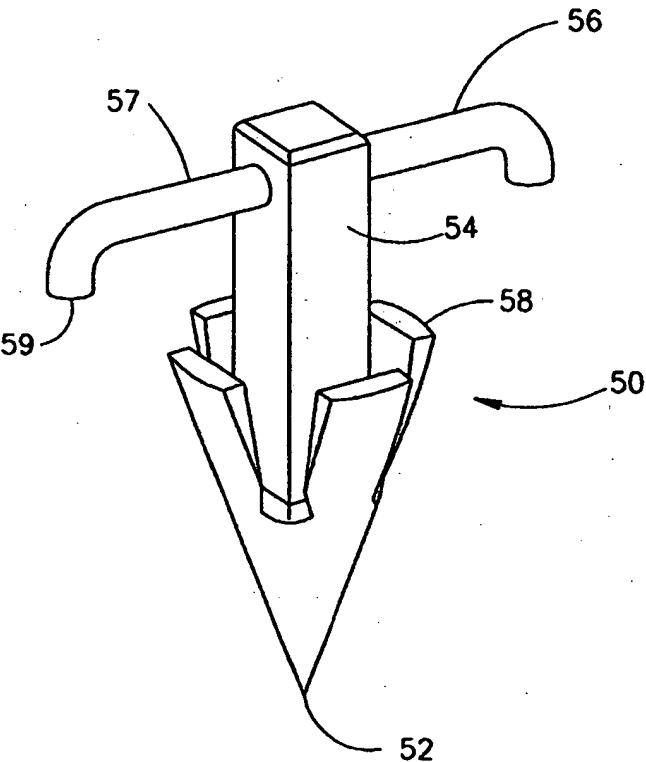


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(54) Title: TACK DEVICE (57) Abstract <p>A surgical tack, comprising: a single shaft formed of a bio-compatible material and having a tip adapted for entering and engaging bone; and a head mounted on said shaft, said head adapted for engaging a substrate between said head and said bone. Preferably, said shaft is a separate element from said head. Alternatively or additionally, said head is rotatable relative to said shaft.</p> 		

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TACK DEVICE

FIELD OF THE INVENTION

The present invention relates to methods and apparatus for treating incontinence, especially by bladder neck support.

5

BACKGROUND OF THE INVENTION

Urinary incontinence is an unfortunately common medical complaint. Many treatments have been suggested. Recently, a relatively minimally invasive technique has become more common, in which a bladder neck and/or urethra is supported by a sling, so that the urethra is partially compressed and/or has a support below it so that during straining and/or
10 bladder/urethral descent, pressure is applied between the urethra and the sling, thereby closing its lumen.

Benderev et. al, in U.S. Patent 5,836,314 and Brenneiman et al, in PCT publication WO 98/19606, the disclosures of which are incorporated herein by reference, describe exemplary procedures for treating incontinence. Two or more bone anchors are attached to the pubic
15 bone. Each anchor is pre-threaded with a suture. Brenneiman suggests attaching a sling to the sutures such that when the sutures are pulled tight and knotted, the sling is urged towards the pubic bone. Benderev suggests integrally molding one end of a suture with a "suture support", which suture support is provided to prevent damage to the urethra by the sutures.

It should be noted that, prior to the introduction of slings, some earlier procedures, for
20 example the Burch procedure and the M.M.K. procedure, used only sutures without a sling to support the bladder neck. Also the, different, needle bladder neck suspension procedure uses only sutures. The disadvantage of these procedures is that the bare sutures can cut into and damage the urethra. In a sling procedure, described below, a mesh or a wide strip of material contacts the urethra instead of sutures, so that the urethra is not damaged.

25 Fig. 1 is a schematic side cut-through illustration of a pubic region 20 during such a procedure, before the sutures are tightened. In the figure, a sling 32 is located between a vagina 22 and a bladder neck 26 of a bladder 24. The sling is threaded by a plurality of sutures 36, which are attached to a bone anchor 30, in a pubic bone 28.

There are two commonly applied methods of bringing sling 32 to a position between
30 vagina 22 and bladder neck 26. In a first method, an incision is made in the vagina, at an area corresponding to that marked with reference number 34, perpendicular to the figure plane, thereby forming a flap. The sling is inserted into the incision, under the flap, and after the sling is tightened, the incision is closed. In a second method, only a small hole in the vagina lining

is made for each inserted bone anchor and a tunnel is formed between the two holes, for insertion of sling 32 therethrough.

This family of suture-sling techniques has several disadvantages:

5 (a) the suture is an additional element which may be damaged during the procedure or after it;

(b) knotting the sutures (after they are tightened) takes skill and time; additionally, some patients have complained that the sutures cause discomfort during sexual activity, since such sutures typically have sharp edges and are often bulky as the suture may have to be knotted as many as six times to assure patency;

10 (c) the sutures add some unwanted leeway between the positioning of the anchors and the positioning of the ends of the sling; and

(d) the sutures may damage the sling by cutting through it (older tissue being more susceptible); if the suture enters the sling at multiple points (to reduce strain at the sling-suture joints) the sling may be deformed by the sutures.

15 U.S. Patent 3,580,313, to McKnight, the disclosure of which is incorporated herein by reference, suggests using the tissue between the urethra and the vagina as a "sling" and stapling that tissue to the pubic bone. However, this solution may not be suitable for some patients, such as older patients, as their tissue are usually too weak to provide a suitable support. Also, older tissue is more susceptible to cut-through damage from the staples.

20 SUMMARY OF THE INVENTION

An aspect of some preferred embodiments of the present invention relates to a sutureless method of supporting a bladder neck. In a preferred embodiment of the invention, the bladder neck is supported by a sling, and the sling is directly tacked to a pubic bone, without intermediate sutures. Alternatively or additionally, the sling is directly attached to the
25 bone using other means, for example an adhesive. As used herein "directly attached" means attached without an intermediate suture. In many cases, the sling will not be in direct physical contact with the bone. Generally, but not necessarily, there will be only tissue (if any) between the sling and the bone. However, in a preferred embodiment of the invention, there will not be a suture or other implant between the sling and the bone.

30 It is noted that by not requiring sutures, the previously required step of tightening and tying the sutures is not required.

An aspect of some preferred embodiments of the invention relates to a sling that is preloaded with one or more tacks at one or both ends thereof prior to insertion into a body. In a preferred embodiment of the invention, the pre-loaded sling is mounted on a tacker, for

insertion into the body. Alternatively, the sling is not provided as pre-mounted on a tack and is mounted on a tack only after the tack is mounted on a tacker with a protruding tack. Optionally, the mounting of the sling is a two step process, in which the tack is assembled after the sling is mounted on it.

5 An aspect of some preferred embodiments of the invention relates to tacks with wide heads. In a preferred embodiment of the invention, a tack comprises a shaft and a head, where the head has a maximum extent perpendicular to the shaft, which extent (the width of the head) is considerably greater the shaft diameter. Alternatively or additionally, the width of the head is made considerably greater than a maximum extent of a bone-entering portion of the tack
10 (which is usually wider than the shaft). Thus, the head is larger than the hole formed in the sling by its being tacked and the head can maintain the sling in place. In a preferred embodiment of the invention, the head is substantially circular or polygonal. Alternatively, the head is a bar-shaped beam which is perpendicular to the shaft. As used herein "considerably larger" means 50%, 100%, 200%, 400% larger or more. Although the head may be large, it is
15 not necessarily solid. Rather, one or more holes may be formed in the head. Optionally, these holes are used for threading the sling through them.

In some preferred embodiments of the invention the head can rotate relative to the shaft.

20 An aspect of some preferred embodiments of the invention relates to disassembled or deformable tacks, in which a sling may be pierced with a small diameter portion of the tack. The tack is then assembled or deformed, so that the head and/or bone entering portions of the tack have a larger diameter than the piercing portion. In one example, the tack comprises two parts, a head with a shaft portion and a bone-entering portion. The sling is pierced by the shaft
25 portion and then the bone-entering portion is attached to a protruding end of the tack. In another embodiment, the bone-entering portion is maintained at a small diameter until after it pierces the sling, for example by a fin in the shaft receding into a recess formed in the shaft or by the shaft being expandable. In another example, the head is separate from the shaft.

30 An aspect of some preferred embodiments of the invention relates to an attachment to a bone stapler, which attachment holds a sling in place over a staple-exit portion of the stapler, to enable a standard stapler or a standard bone-anchor inserter to be used for tacking slings in accordance with a preferred embodiment of the invention. In a preferred embodiment of the invention, the type of stapler provided is such that the tip of the staple does not protrude from the stapler, so the sling is preferably maintained in place solely by the attachment. In an alternative embodiment, the tip of the staple does protrude from the stapler and may serve to at

least partially hold the sling, while the attachment fixes the orientation of the sling relative to the staple or the attachment. If a two prong staple (or tack) is used, such an attachment may serve solely to keep the sling from slipping off the tip of the staple.

5 An aspect, of some preferred embodiments of the invention, relates to a tacker which includes two stapling heads, for simultaneous tacking of two sides of a sling. In a preferred embodiment of the invention, the tacker comprises two arms, with a tacking head at the end of each arm. Preferably the angle between the arms is controllable to adapt the tacker for different length slings. In a preferred embodiment of the invention, the sling is pre-mounted on the two heads prior to insertion into the body.

10 There is thus provided in accordance with a preferred embodiment of the invention, a surgical tack, comprising:

a single shaft formed of a bio-compatible material and having a tip adapted for entering and engaging bone; and

15 a head mounted on said shaft, said head adapted for engaging a substrate between said head and said bone. Preferably, said shaft is a separate element from said head. Preferably, said head is rotatable relative to said shaft. Alternatively or additionally, said head is mounted in a slot defined at an end of said shaft. Alternatively or additionally, said head is mounted on a narrowing of said shaft.

20 In a preferred embodiment of the invention, said head comprises only one arm extending substantially perpendicular to said shaft.

In a preferred embodiment of the invention, said head comprises at least two arms extending substantially perpendicular to said shaft. Alternatively, said head comprises at least one arm extending at an angle to said shaft.

25 In a preferred embodiment of the invention, said head defines a plurality of apertures therethrough. Alternatively or additionally, said head comprises a plurality of protrusions extending in a direction of said tip, which protrusions are adapted for engaging said substrate. Preferably, said protrusions are smooth at a portion thereof where they engage said substrate. Alternatively, said protrusions are pointed at a portion thereof where they engage said substrate.

30 In a preferred embodiment of the invention, said protrusions extend least half a thickness of the substrate.

In a preferred embodiment of the invention, the tack comprises at least one fin extending from said shaft, distal from said head, and adapted for engaging said bone after insertion of said shaft into said bone. Preferably, said at least one fin comprises at least two

angularly spaced apart fins. Alternatively or additionally, said at least one fin comprises at least two axially spaced apart fins. Alternatively or additionally, said at least one fin comprises a separate element from said shaft. Alternatively, said at least one fin is integrally formed with said shaft.

5 In a preferred embodiment of the invention, said shaft defines a recess and said at least one fin is adapted for recessing into said defined recess, when force having a vector perpendicular to said shaft is applied to said fin.

In a preferred embodiment of the invention, said at least one fin is mounted on a separate fin element, which is attached to said shaft.

10 In a preferred embodiment of the invention, said head is roughened at a portion thereof that engages said substrate.

In a preferred embodiment of the invention, said tack comprises an advance-stop on said shaft adjacent said head and separate from said head, such that said advance-stop prevents said head, at portions near said shaft, from touching said bone. Alternatively or additionally,
15 said head has two configurations, one in which it has an substantially large transaxial extent and one in which it has a substantially small transaxial extent.

There is also provided in accordance with a preferred embodiment of the invention, a tack insertion device, comprising:

a "C" shaped body;
20 a handle at one end of said body;
a slotted tack holder at a second end of said body, wherein said slotted tack holder holds a tack pointed towards said handle and wherein said slot is adapted for frictionally engaging a tack.

Preferably, said slotted head is adapted to engage a tack having a multi-arm head.
25 Alternatively or additionally, said slotted head is adapted to engage a tack having an apertured head.

In a preferred embodiment of the invention, said device comprises a second tack holder attached to said body at an offset from said first tack holder. Preferably, said device comprises a selectable offsetting mechanism for setting said offset.

30 In a preferred embodiment of the invention, said device comprises a safety release mechanism that prevents the release of said tack.

There is also provided in accordance with a preferred embodiment of the invention, a method of preparing a sling combination, comprising:

providing a sling formed of a biocompatible material and having two ends;

mounting said sling on a first tack at a first end of the sling; and

mounting said first tack on a tacking device. Preferably, said method comprises mounting said sling on a second tack at a second end of said sling. Preferably, said method comprises mounting said second tack on said tacking device.

5 In a preferred embodiment of the invention, said method comprises adjusting an offset between two tacking heads of said tacking device.

In a preferred embodiment of the invention, said method comprises cutting said sling to said after mounting said first tack on said sling.

10 In a preferred embodiment of the invention, mounting said sling on said first tack is performed after said tack is mounted on said tacking device. Alternatively, mounting said sling on said first tack is performed before said tack is mounted on said tacking device.

In a preferred embodiment of the invention, the method comprises assembling said first tack after mounting said sling on said first tack. Alternatively, the method comprises assembling said first tack after mounting said first tack on said tacking device.

15 Preferably, assembling said first tack comprises attaching a head to a shaft of said tack. Alternatively or additionally, assembling said first tack comprises attaching at least one fin to a shaft of said tack.

In a preferred embodiment of the invention, mounting said sling on said tack comprises piercing said sling by said tack. Alternatively, mounting said sling on said tack comprises
20 inserting said tack into a hole in said sling.

In a preferred embodiment of the invention, the method comprises inserting at least a part of said tacking device into a human vagina, after mounting said tack on the tacking device.

25 There is also provided in accordance with a preferred embodiment of the invention, a kit, comprising:

a sling having a length suitable for bladder neck supporting; and

at least one tack, having a head and a shaft, wherein said head has an extent perpendicular to the shaft, which extent is substantially greater than a diameter of the shaft. Preferably, said sling contains at least one pre-punched aperture. Alternatively or additionally,
30 said sling contains at least two adjacent pre-punched apertures, for setting an effective sling size.

In a preferred embodiment of the invention, said at least one tack comprises at least two tacks. Alternatively or additionally, said sling is reinforced at least at its ends.

There is also provided in accordance with a preferred embodiment of the invention, a kit, comprising:

a sling formed of bio-compatible material and having a length and mechanical properties suitable for bladder neck supporting; and

5 a clip adapted to hold said sling against a tacking head of at least a particular tacking or stapling device.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more clearly understood from the following detailed description of the preferred embodiments of the invention and from the attached drawings, in
10 which:

Fig. 1 is a schematic cut-through illustration of a pubic area during a prior art bladder neck support operation;

Fig. 2 is a schematic cut-through illustration of a pubic area during a bladder neck support operation, in accordance with a preferred embodiment of the invention;

15 Fig. 3 is a schematic illustration of a tack for attaching a sling to a bone, in accordance with a preferred embodiment of the invention;

Fig. 4 is a schematic illustration of a two part tack for attaching a sling to a bone, in accordance with a preferred embodiment of the invention;

Fig. 5 is a schematic illustration of a tacker for attaching the tack of Fig. 3;

20 Fig. 6 is a blow-up of a tacking head part of the tacker of Fig. 5;

Fig. 7 illustrates a tack which is preloaded on a sling and mounted on a tacker, in accordance with a preferred embodiment of the invention;

Fig. 8 is a schematic illustration of a two-headed tacker, in accordance with a preferred embodiment of the invention;

25 Figs. 9A-9D illustrate an alternative tack, in accordance with a preferred embodiment of the invention;

Fig. 10, which corresponds to Fig. 6, illustrates the mounting of the tack of Figs. 9A-9D on a tacker;

30 Figs. 11A-11B illustrate a variation of the tack of Figs. 9A-9D, in accordance with a preferred embodiment of the invention;

Figs. 12A-12C illustrate variations of the head of a tack, in accordance with alternative preferred embodiments of the invention;

Figs. 13A and 13B illustrate a recessed fin tack, in accordance with a preferred embodiment of the invention;

Figs. 13C and 13D illustrate an expanding head tack, in accordance with a preferred embodiment of the invention; and

Fig. 14 is a schematic illustration of a sling grasping attachment for a stapler, in accordance with a preferred embodiment of the invention.

5 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

Fig. 2 is a schematic cut-through illustration of a pubic area during a bladder neck support operation, in accordance with a preferred embodiment of the invention. A sling 40 is shown as being tacked directly to pubic bone 28, by a tack 42 and being held in place by a head 44 of tack 42. In a preferred embodiment of the invention, a shaft of tack 42 pierces sling
10 40. Alternatively or additionally, the sling is held against the bone by friction, caused by head 44 urging sling 40 against pubic bone 28 (possibly through intervening tissue).

In a preferred embodiment of the invention, the following method is used to attach the sling to the bone:

(a) a first tack is tacked (preferably through sling 40) into a first location on pubic bone
15 28;

(b) the sling is inserted between vagina 22 and bladder neck 26 or the urethra: access is preferably via one or more incisions in the vaginal wall;

(c) a second tack is tacked through the sling and into a second location on the pubic bone; and

20 (d) any incisions in the vagina are preferably closed, e.g., sewn up.

The above method may be varied in accordance with various preferred embodiments of the invention. In particular, the order of steps may be changed and steps may be combined. In one example, the two tacks may be tacked simultaneously, using a two-headed tacker, as described for example with reference to Fig. 8.

25 In a preferred embodiment of the invention, the sling comprises a strip of xenograft material. Alternatively or additionally, the sling comprises human cadaver tissue or auto-graft material harvested from the patient. Alternatively or additionally, the sling comprises a synthetic material, for example Dacron mesh. In a preferred embodiment of the invention, the sling is about 1 mm thick, 1-2 cm wide and 5.5 cm long, between the tacked points. It should
30 be appreciated however, that the exact dimensions of the sling may vary responsive to the anatomy of the patient being treated. Possibly, a prior-art sling may be utilized.

In a preferred embodiment of the invention, the sling is reinforced at or near portions thereof through which the tack is inserted and/or portions of the sling engaged by head 44. Alternatively, the sling is not reinforced. Alternatively or additionally, a hole is pre-punched in

the sling at or near where the insertion point of the tack. Possibly, the hole is reinforced. The hole may have a shape similar to the cross-section of the shaft or it may be larger or smaller than the cross-section and/or of a different shape. In a preferred embodiment of the invention, one or more slits are formed (and optionally reinforced) in the sling at locations where the tack is to be inserted instead of- or in addition to- punching a hole thereat. Alternatively or additionally, an elliptical or a long rectangular slot may be cut in the strip to accommodate a plurality of tack positions. Alternatively or additionally, a plurality of pre-punched holes and/or pre-cut slits may be provided for that purpose. Excess sling length is optionally removed either prior to or after deployment of the sling. Alternatively or additionally, the sling is formed of two parts, that are glued together to form a sling of a desired length, prior to or after being tacked to the bone.

In a preferred embodiment of the invention, human cadaver based slings do not have pre-provided holes, while synthetic slings do. In some cases, holes are cut just prior to the procedure. Alternatively, the holes are cut in a factory.

In a preferred embodiment of the invention, the sling has a smooth surface. Additionally or alternatively, at least one of the two surfaces of the sling is rough, for example to promote tissue ingrowth. Additionally or alternatively, the sling is coated with tissue growth enhancing or retarding coatings, possibly both, on different parts of the sling. Additionally or alternatively, the sling may have a plurality of barbs, apertures and/or other structures defined thereon to grasp soft tissue, for example the urethra and/or tissue between the urethra and the bone.

In a preferred embodiment of the invention, the sling is pre-loaded on one or both tacks, before the tacking head is inserted into the body. The pre-loading may be performed in a factory or a work shop, where the sling is produced and/or processed. Alternatively, the pre-loading is performed at the operating table, possibly after a desired sling length is determined.

Alternatively, the sling is placed between the tacking head and the bone, inside the body, so that the inserted tack will pass engage the sling before entering the bone. In an exemplary embodiment, one tack is pre-mounted on the sling and is inserted into the bone. The sling is then stretched using a forceps, for example, and a second tack is inserted through the sling into the bone.

In a preferred embodiment of the invention, only two tacks are used, one for each side of the sling. Alternatively, more than two tacks may be used for example, for a wide sling (e.g., two tacks on at least on side of the sling), for an "X" shaped sling or to adjust the length of slings which are not tight enough. In some embodiments, one side is tacked and the other

side is sutured or otherwise attached, for example to assist in adjustment. Alternatively, the two ends of the sling may be tacked together at a single point on pubic bone 28, possibly using a single tack, thereby forming a closed loop of the sling. Preferably, that single point is not at the center of the pubic bone.

5 In a preferred embodiment of the invention, a sling is used to support the bladder neck. Alternatively, such a sling may be provided to support the bladder itself, the urethra and/or other abdominal organs. Bladder support, also known as cystocelle repair, generally requires a wide sling with a plurality of tacks at each end (or wide tacks). Also, such a sling may be used to correct a defect in the abdominal floor from which internal organs protrude, by supporting
10 or suspending such organs. Alternatively or additionally, such a sling may be used for male bladder, urethra or bladder neck suspension. Alternatively or additionally, such a sling may be used for a tongue suspension and/or for suspending other soft tissues in the body.

In a preferred embodiment of the invention, a catheter is inserted into the urethra prior to the procedure, to minimize the risk of accidentally puncturing the urethra. Additionally,
15 such a catheter may be useful when determining a desired sling length.

In a preferred embodiment of the invention, a flap-forming incision (e.g., at location 34) is made in the vagina prior to the first tacking or between the first and second tacking, so that the sling can be brought through the incision, under the flap and into the tissue between the vagina and the urethra. Alternatively, both tacks are tacked (with at least part of the sling
20 still inside the vagina) and then the incision is made in the vagina. In some circumstances, no incision will be made and a significant portion of the sling will remain in the vagina.

Alternatively to making an incision in the vagina, a sub-mucosal tunnel may be formed in the tissue between the vagina and the urethra and the sling and/or a tack device (described below) passed through the tunnel. In a preferred embodiment of the invention, only a single
25 incision is made and the tunnel is made through that incision, for example using an endoscope. Alternatively, two incisions are made and the tunnel formed between them. As described herein, such tunneling preferably utilizes small incisions in the vagina which are either formed by the tacks passing through the vaginal wall to the bone or prepared in advance for the tacks. The tunneling and/or passing may be performed before the first tacking or between the first
30 tacking and the second tacking. When using a tack where the sling is attached to the tack after the tack is inserted into the bone (described below), such tunneling may even be performed after both tacks are attached to the bone.

In a preferred embodiment of the invention, a small incision and/or hole is made in the vagina for the insertion of each tack. Optionally, tissue which intervenes between the vagina

and the pubic bone is moved away from the path of the tack so that the tack compresses only a minimal amount of living tissue (other than the sling) against the pubic bone. Alternatively, the tack may create its own hole in the vaginal wall. As described above, these holes/incisions may be used as an aid to forming a sub-mucosal tunnel which bridges the incisions and is
5 between the vagina and the urethra. In some embodiments of the invention, when a tack is tacked to a bone through the hole, a portion of the sling is pulled, by the tack, out of the vagina and into the hole. In an embodiment where only a single incision is made, both tacks (or only a single one if the tacking is at a single location only) are brought through the same, small, incision.

10 The tacks are preferably attached to the superior pubis ramus (as shown in the figure). Thus, the sling is angled forward (when the patient is standing). If the bladder neck or the urethra descend suddenly, the neck is then held up by the sling. Alternatively, the tacks may be attached to other parts of the pubic bone, for example its bottom or its front, as the tacks may have a flat head which does not cause contact discomfort. Additionally or alternatively,
15 especially for bladder neck suspension procedures, it may be desirable to tack the tacks higher up on the bone or even on the abdominal fascia.

In a preferred embodiment of the invention, the length of the sling is determined prior to the tacking. Alternatively, after the first tack is inserted, a required sling length may be determined and the sling cut to size. Optionally, any trailing portions of the sling which remain
20 after the tacking are cut off.

Fig. 3 is a schematic illustration of a tack 50 for attaching a sling to a bone, in accordance with a preferred embodiment of the invention. Tack 50 includes a sharp tip 52 for entering the bone, a shaft 54 which grasps the sling and a head 56 for preventing the sling from slipping off the shaft and/or for urging the sling against the bone, to prevent relative movement
25 of the sling and the bone. One or more fins 58 may be provided to improve the bone holding characteristics, however, they do generally interfere with insertion into bone. In some embodiments, fins 58 are flexible. In other embodiments, they are rigid. Alternatively, other constructions for bone piecing and grasping tips, as known in the art, may be used, for example screw-tipped inserts. In a preferred embodiment of the invention, head 56 comprises a
30 pair of extending arms 57. At the tip of each arm (or elsewhere along their length) a protrusion 59 is preferably provided. as will be shown below, sling 40 is preferably urged by protrusions 59 against the bone, however, the entire head may do the urging. Protrusions 59 are preferably flat at their contact point with sling 40. Alternatively, they may be pointed or roughened. Possibly, holes are formed in sling 40 (prior to, during or after insertion), so that at least some

of protrusions 59 transfix sling 40 through these holes. Head 56 is preferably flat, however, in some embodiments it may protrude, especially for covering up sharp angles in the head.

In a preferred embodiment of the invention, the arms are perpendicular to the shaft. Alternatively, they may be angled, towards the tip or away from the tip, for example, 10°, 20°, 5 30° or 45° away from a perpendicular to the shaft. Thus, the tips of the arms can mimic the behavior of protrusions 59. Preferably the arms are super elastic, however, they can also function correctly if they are elastic, plastic or shape memory. The arms may be in the plane of the shaft or outside of the shaft plane, possibly not parallel to the shaft plane.

In a preferred embodiment of the invention, a head 56 is wide, for example a circular 10 plate, a sphere or a half-sphere. In some embodiments, the wide head comprises an expanding head, which, once the tack exits the tacker, expands and/or unfolds to have a wide extent. Preferably, the folded/unexpanded head has a diameter similar to that of the shaft, so that the tack is suitable for use in existing anchor insertion devices. In one example, the unfolding head comprises a super-elastic material which is maintained at a deformed (small head diameter) 15 configuration by the tacker. In another example, the expanding head is expanded as a result of pressures applied during the insertion into the bone, for example pressure applied by an anvil portion of the tacker which forces the tack into the bone (described below).

One possible disadvantage of the tack of Fig. 3 is that the diameter of the shaft is smaller than the diameter of the tip. Thus, when the sling is loaded onto the tack, the tip may 20 rip a larger-than-necessary hole in the sling. In some cases, the sling is sufficiently flexible and/or elastic to accommodate the tip.

In a preferred embodiment of the invention, it may be desirable to provide a two part tack, such as tack shown in Fig. 4 as a tack 60, in which a head 66 and a shaft 62 form a first portion, having a small diameter and on which the sling is skewered. Once the sling is 25 skewered by shaft 62, a bone engagement portion 64 is mounted on shaft 62, to form a complete tack 60. The end result is thus a tack on which a sling, with only a small hole therethrough, is loaded. In some embodiments, head 66 is separate from shaft 62.

Alternatively to using a dedicated tack, a commonly available staple, for example a "U" type staple may also be used to tack the sling to the pubic bone. Thus, the tack may have 30 two or more legs that engage the bone. Possibly however, the quality of the attachment is lower. For example, there may be an increased strain on the sling.

Possibly, the sling is not pierced by the tack at all. Rather the sling is provided between the two or more shafts of the tack (or legs of a staple) and is urged against the bone by the head of the tack and held thereat by friction. Preferably, the portion of the head of the tack that

engages the sling is rough or jagged, to better grasp the sling. Additionally or alternatively, a stop is provided on the one or more legs, so that a minimal space is provided between the bone and the head of the tack, for example to prevent undue compression of intervening soft tissue. Additionally or alternatively, the sling may be captured between the shaft and the bone, for example, the shaft has a depression formed in its side and the sling is held between the depression and the portion of the bone which is inside the hole made by the tack. Alternatively or additionally, the sling may be held by holes in the head of the tack (described below).

Additionally or alternatively to using a tack, some preferred embodiments of the invention contemplate other methods of attaching the sling directly to the bone, for example using a quick setting adhesive.

In a preferred embodiment of the invention, once the tack is inserted into the bone, the sling is firmly attached to the bone. In some embodiments of the invention, however, the sling may be fixed to the tack after the tack is attached to the bone. In one example, similar to that of Fig. 4, a thin-headed tack is attached to the bone and only then is the sling loaded onto the tack. Thereafter, the head of the tack is attached and/or expanded, to snugly grasp the sling.

In a preferred embodiment of the invention, a guiding wire or suture is attached to the tack, so that the sling can be guided along the guide wire to the tack, for properly engaging it with the tack head. This wire may then be removed from the tack, as it does not structurally interconnect the tack and the sling. This embodiment is useful for example if the exact length of the sling is not known in advance. Preferably, the sling has a plurality of holes formed therein, to engage the shaft of the headless tack at various positions along the sling.

Fig. 5 is a schematic illustration of a tacker 70 for attaching the tack 50 of Fig. 3 to pubic bone 28. Tacker 70 preferably comprises a handle 72, a body 74, which is preferably curved and adapted for use in the vagina and a head 76, which is urged against the pubic bone for inserting a tack. In this embodiment, a tack 50 is mounted at least partially externally to the head. In other embodiments, the tack may be partially or completely recessed inside head 76. Alternatively or additionally, a flexible protecting cover is provided, which cover is pushed back from the tip of the tack to the direction of the head of the tack, by the bone when the tack is pressed against the bone. In a preferred embodiment of the invention, a cartridge of such tacks is attached to head 76 or enclosed in body 74.

In a preferred embodiment of the invention, tack 50 is held onto head 76 by friction, such that, once it is engaged by the bone it can be removed from head 76. Alternatively, a release mechanism (not shown) for preventing the release of the tack may be provided. Alternatively or additionally, such a release mechanism may prevent the tops of fins 58 from

exiting the tacker, so that the tack cannot be irrevocably attached to the bone, without activating the mechanism. Preferably, force is applied to the tack by pulling up handle 72, thereby directly pulling back tack 50 into the bone. Alternatively, tacker 70 may include a mechanism for advancing tack 50 into the bone, for example a lever based mechanism or a pneumatic mechanism. In devices with a release or a safety mechanism, the mechanism is preferably released prior to applying the force or during the force application, for example by a lever on handle 72 (not shown).

Fig. 6 is a blow-up of tacking head 76 part of the tacker 70 of Fig. 5. A slot 71 is preferably formed in head 76, to hold arms 57 for the tack configuration shown.

Fig. 7 illustrates a tack 50, preloaded on a sling 40 and preloaded on the tacker, in accordance with a preferred embodiment of the invention.

Fig. 8 is a schematic illustration of a two-headed tacker 80, in accordance with a preferred embodiment of the invention. Tacker 80 includes two arms, an arm 82 and an arm 84, each with a tacking head, 86 and 88, respectively. In a preferred embodiment of the invention, the distance between the tacking heads may be controlled using a screw 90. Screw 90 may set a maximum and/or minimum distance between the tack heads or it may fix the distance between the tack heads. In one embodiment of the invention, the sling is preloaded on the tacks on the two tacking heads, the two heads are placed in the vagina and the two tacks are simultaneously tacked into the pubic bone. An incision for bringing the sling outside the vagina may be made before or after the tacking. Alternatively, the sling is first brought into the desired area between the vagina and the urethra, possibly using a tunnel and then the sling is loaded (or not) onto the tacks and the tacks are attached to the bone.

In a preferred embodiment of the invention, tacker 80 includes only a single handle 92, which utilizes a single mechanism for advancing both tacks (if such mechanism is provided). Alternatively, the handle includes two separate mechanisms. Alternatively, also a second handle 93 is provided. Each of handles 92 and 93 may have a separate mechanism.

Alternatively to attaching the tacks substantially simultaneously, the tacker may be used to attach the tacks in series, first one and then the other. Optionally, screw 90 includes a sliding mechanism for allowing only one of the two handles to be retracted at a time without also advancing the tack of the other handle. In a preferred embodiment of the invention, setting screw 90 supports fixing the length of the sling outside the body, by setting the distance between the tacking heads (and thus, typically, the tacks).

Figs. 9A-9D illustrate an alternative tack 100, in accordance with a preferred embodiment of the invention. Fig. 9A is a perspective view of tack 100, showing a tip 102 of a

shaft 104, two fins 108 and a head 106, connected to shaft 106 by crimping an extension 112 of shaft 104 to engage a ring portion 110 of head 106. In a preferred embodiment of the invention, head 106 comprises two arms 107, having one or more apertures 105 formed therein. A protrusion 109, preferably wedge shaped, is provided at the end of each arm 107.

5 Optionally, instead of sling 40 being transfixated by shaft 104, sling 40 may be threaded through apertures 105 and/or sutured thereto. Preferably, any knot in the suture is placed between head 106 and the bone.

 In a preferred embodiment of the invention, such slings are provided pre-sutured. In a preferred embodiment of the invention, the sutures are in the form of a loop (through which

10 shaft 106 is preferably passed). Such a loop are preferably shortened by knotting, if needed. Alternatively, the sutures are not looped. Such pre-sutured slings may also be used for prior art sling procedures.

 Fig. 9B is a top view of tack 100.

 Fig. 9C is a side view along the direction of line B-B (Fig. 9B) of tack 100.

15 Fig. 9D is a cross-section along line B-B (Fig. 9B) illustrating the crimping of extension 112 over ring 110. In a preferred embodiment of the invention, head 106 is thus free to rotate relative to shaft 104, however, this freedom is not essential in all embodiments and may even be explicitly blocked, for example by forming a notch in ring 100.

 Fig. 10, which corresponds to Fig. 6, illustrates the mounting on a tacker 120 of tack

20 100. A slot 122 formed in the head of tacker 120 is preferably configured so the head fits in apertures 105, by slot 122 matching a pair of arms 124 that extend between ring 110 and the rest of head 106.

 Figs. 11A-13B illustrate variations in tack designs.

 Fig. 11A is a top view of a tack 130 having four arms 132 (rather than two).

25 Alternatively, other numbers of arms, for example three may be provided. Arms 132 are preferably symmetrically arranged and all of a same length, however, this is not essential and in some embodiments one arm may be shorter or two arms may be closer together than the other arms.

 Fig. 11B is a cross-sectional view of a tack 140, corresponding to Fig. 9D and showing

30 an alternative method of attaching a head 142 to a shaft 144, for any type of tack, in which a slot 146 is formed in shaft 144, to receive head 142. An advantage of this method is that an incorrectly placed tack may be corrected by removing the head and advancing the shaft so it is completely enclosed by the bone. In a preferred embodiment of the invention, the head is super-elastic or elastic, so that by applying enough force it can be mounted on the shaft or

removed, without permanently distorting it. Alternatively, one time elastic or plastic heads are used, alternatively, a shape-memory material may be used.

Figs. 12A-12C illustrates variations of head portions of tacks. Fig. 12A illustrates a head 150 which defines a plurality of apertures 152 therein and has a plurality of protrusions 156 around its perimeter (and also possibly inside the perimeter), which are protrude towards the bone. Central aperture 154 is preferably used to affix head 150 to a shaft of a tack. The apertures may or may not be aligned with the protrusions that most forcefully engage the sling.

Fig. 12B illustrates, in top view, a tack 160, which comprises spiral arms 162, rather than straight arms as described above. An advantage of spiral arms is an increased flexibility of the arms, without compromising their strength. A pair of fins 164 are also shown, for example of the type used in device 100 of Fig. 9.

Fig. 12C illustrates, in top view, a tack 170, which has only a single arm 174. A pair of fins 174 is also shown, perpendicular to the arm. Alternatively, the fins are parallel or oblique to the arm. Alternatively, only one fin 174, preferably opposite arm 172, is used.

Figs. 13A and 13B illustrate a recessed fin tack 180, in accordance with a preferred embodiment of the invention. Tack 180 comprises a head 190 attached to a shaft 182 with a tip 184. At least one fin 186, but possibly more than one, extend from shaft 182, as shown in Fig. 13A. In a preferred embodiment of the invention, a recess 188 is formed in shaft 182, to receive fin 182 during insertion into the bone, so fin 186 does not impede the insertion process (Fig. 13B). Preferably, during insertion, the edge of the bone presses fin 182 into recess 188. In a preferred embodiment of the invention, shaft 182 or fin 186 is formed of an elastic, shape-memory or super-elastic material, to assure that fin 186 returns to an extended configuration as shown in Fig. 13A.

Figs. 13C and 13D illustrate an expanding head tack 200, in accordance with a preferred embodiment of the invention. Tack 200 comprises a shaft 202, preferably with a plurality of fins 206 at its tips. The head of tack 200 comprises two distortable parts 210. As shown, two or more separate arms are provided, possibly each one with a protrusion as in some of the previous embodiments. Alternatively, an extension of shaft 202 may be split. When the tack is inserted the head may be narrow, as shown in Fig. 13C. When the tack is inserted into a bone, the head is split, for example using a cone shaped element 212, resulting in a tack as shown in Fig. 13D, which can be substantially the same as the tack of Fig. 3. In a preferred embodiment of the invention, an advance-stop 208 is provided, to prevent shaft 202 from advancing too far, especially while portions 210 are being split apart. Such a stop may also be provided in other tack design, for example to provide a minimum distance between the

head and the bone. Alternatively, the advance stop is part of the tacking head, for example being in the form of forceps or a "C" shaped element which space the head from the bone and is removed with the tacking head. Possibly, the advance stop is formed of an bio-absorbable material.

5 In a preferred embodiment of the invention, advance-stop 208 extends away from shaft 202, at least in one transaxial direction, more than portions 210 in their unexpanded configuration. In a preferred embodiment of the invention, a slotted insertion device pushes against advance-stop 208 and an additional internal mandrel is provided to serve as element 212. Thus, portions 210 are distorted plastically. Alternatively, the portions may be formed of
10 a shape-memory material (which can be optionally heated by the tacking head). Alternatively, the portions may be elastic or super-elastic. Preferably, the portions are maintained in their narrow configuration by the slotting head, which, when removed, allow them to snap open to their wide configuration. Alternatively or additionally, a bi-stable or a bimetal-mechanism for configuration change may be used. Such elastic, plastic, shape-memory, super-elastic or other
15 head distorting mechanism may be used with any of the tack-heads described above.

Additional variations in tack design are also contemplated in accordance with preferred embodiments of the invention. For example, the shaft of the tack may have a fixed or a varying profile, which can be, for example, circular, square, rectangular, triangular, fluted and/or spiral. Also, the shaft may be barbed and/or roughened. The tip of the tack may be, for
20 example, smooth, fluted, threaded, spiral, inclined on some sides and flat on the others. Alternatively or additionally, the tip may be oblique, for example as shown in Fig. 13. The fins may be, for example, of a design that is rigid or that folds back towards the shaft during insertion. The arms of the head may be, for example, perpendicular to the shaft or they may be slanted. Possibly, the arm configuration is designed to match a anatomical geometry, such as a
25 bone incline. The fins may be distributed with a rotational symmetry around the shaft axis. Alternatively, they are not. Alternatively or additionally, the fins are all at a same axial position along the shaft. In some embodiments, they are not.

Fig. 14 is a schematic illustration of a sling grasping attachment 904 for a stapler 900, in accordance with a preferred embodiment of the invention. As described above, in some
30 cases, even a standard type staple, bone anchor and/or bone screw may be used to attach sling 40 directly to the bone. Such screws and staples usually include a stop for limiting the penetration depth into the bone, which can serve as a tack "head", in accordance with a preferred embodiment of the invention. The portion of a shaft behind the stop, including for example a threadable hole, may be filed off, especially if they are not required for the

structural integrity of the bone insert. However, the standardized staplers, anchor insertion devices and other bone attachment apparatus do not appear to provide for a sling that is engaged by the staple. Attachment 904, is an example of an attachment which maintains the sling in a desired position and/or orientation relative to the staple, until the staple is inserted
5 into the bone. In this embodiment, attachment 904 comprises a resilient clip that urges and holds the sling against the body of stapler 900. In other embodiments, the attachment may be mounted over the tacking head, possibly extending the head length. In some cases, for example as shown, a staple 906 may pierce the sling, prior to the act of stapling. In other cases, the tip of the staple is recessed in the stapler and cannot engage the sling. In other embodiments of the
10 invention, other attachments may be provided. In particular, the exact geometry of the attachment may be adapted for a particular stapler model and/or staple type.

In a preferred embodiment of the invention, the above described slings and tacks are provided as a kit which includes one or more slings of possibly varying lengths and two or more tacks.

15 Although the above description has focused on female urinary incontinence, a same procedure and apparatus may be used for male incontinence, for example, by attaching the sling to a descending ramous of the pubic bone through an incision in the perineal area.

It will be appreciated that the above described apparatus and methods of incontinence treatment may be varied in many ways. In addition, a multiplicity of various features, both of
20 methods and of devices, have been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar preferred embodiment of the invention. Further, combinations of the above features are also considered to be within the scope of some preferred embodiments of the invention. It should also be appreciated that many of the
25 embodiments are described only as methods or only as apparatus. The scope of the invention also covers machines for creating the devices. In addition, the scope of the invention includes methods of using, constructing, calibrating and/or maintaining the apparatus described herein. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

CLAIMS

1. A surgical tack for attaching a substrate to a bone, comprising:
a single shaft formed of a bio-compatible material and having a tip adapted for entering
5 and engaging bone; and
a head mounted on said shaft, said head adapted for engaging a substrate between said
head and said bone.
2. A tack according to claim 1, wherein said shaft is a separate element from said head.
- 10 3. A tack according to claim 2, wherein said head is rotatable relative to said shaft.
4. A tack according to any of claims 2-3, wherein said head is mounted in a slot defined at
an end of said shaft.
- 15 5. A tack according to any of claims 2-4, wherein said head is mounted on a narrowing of
said shaft.
6. A tack according to any of claims 1-5, wherein said head comprises only one arm
20 extending substantially perpendicular to said shaft.
7. A tack according to any of claims 1-5, wherein said head comprises at least two arms
extending substantially perpendicular to said shaft.
- 25 8. A tack according to any of claims 1-5, wherein said head comprises at least one arm
extending at an angle to said shaft.
9. A tack according to any of claims 1-8, wherein said head defines a plurality of
apertures therethrough.
- 30 10. A tack according to any of claims 1-9, wherein said head comprises a plurality of
protrusions extending in a direction of said tip, which protrusions are adapted for engaging
said substrate.

11. A tack according to claim 10, wherein said protrusions are smooth at a portion thereof where they engage said substrate.
12. A tack according to claim 10, wherein said protrusions are pointed at a portion thereof
5 where they engage said substrate.
13. A tack according to any of claims 10-12, wherein said protrusions extend at least half a thickness of the substrate.
- 10 14. A tack according to any of claims 1-13, comprising at least one fin extending from said shaft, distal from said head, and adapted for engaging said bone after insertion of said shaft into said bone.
15. A tack according to claim 14, wherein said at least one fin comprises at least two
15 angularly spaced apart fins.
16. A tack according to claim 14, wherein said at least one fin comprises at least two axially spaced apart fins.
- 20 17. A tack according to any of claims 14-16, wherein said at least one fin comprises a separate element from said shaft.
18. A tack according to any of claims 14-16, wherein said at least one fin is integrally formed with said shaft.
- 25 19. A tack according to any of claims 14-18, wherein said shaft defines a recess and wherein said at least one fin is adapted for recessing into said defined recess, when force having a vector perpendicular to said shaft is applied to said fin.
- 30 20. A tack according to claim 14, wherein said at least one fin is mounted on a separate fin element, which is attached to said shaft.
21. A tack according to any of claims 1-20, wherein said head is roughened at a portion thereof that engages said substrate.

22. A tack according to any of claims 1-21, comprising an advance-stop on said shaft adjacent said head and separate from said head, such that said advance-stop prevents said head, at portions near said shaft, from touching said bone.
- 5
23. A tack according to any of claims 1-22, wherein said head has two configurations, one in which it has a substantially large transaxial extent and one in which it has a substantially small transaxial extent.
- 10 24. A tack insertion device, comprising:
a "C" shaped body;
a handle at one end of said body;
a slotted tack holder at a second end of said body, wherein said slotted tack holder holds a tack pointed towards said handle and wherein said slot is adapted for frictionally
15 engaging a tack.
25. A device according to claim 24, wherein said slotted head is adapted to engage a tack having a multi-arm head.
- 20 26. A device according to claim 24, wherein said slotted head is adapted to engage a tack having an apertured head.
27. A device according to any of claims 24-26, comprising a second tack holder attached to said body at an offset from said first tack holder.
- 25
28. A device according to claim 27, wherein said device comprises a selectable offsetting mechanism for setting said offset.
29. A device according to any of claims 24-28, wherein said device comprises a safety
30 release mechanism that prevents the release of said tack.
30. A method of preparing a sling combination, comprising:
providing a sling formed of a biocompatible material and having two ends;
mounting said sling on a first tack at a first end of the sling; and

mounting said first tack on a tacking device.

31. A method according to claim 30, comprising mounting said sling on a second tack at a second end of said sling.

5

32. A method according to claim 31, comprising mounting said second tack on said tacking device.

33. A method according to any of claims 30-32, comprising adjusting an offset between
10 two tacking heads of said tacking device.

34. A method according to any of claims 30-33, comprising cutting said sling to size after mounting said first tack on said sling.

15 35. A method according to any of claims 30-34, wherein mounting said sling on said first tack is performed after said tack is mounted on said tacking device.

36. A method according to any of claims 30-34, wherein mounting said sling on said first tack is performed before said tack is mounted on said tacking device.

20

37. A method according to any of claims 30-36, comprising assembling said first tack after mounting said sling on said first tack.

38. A method according to any of claims 30-36, comprising assembling said first tack after
25 mounting said first tack on said tacking device.

39. A method according to any of claims 37-38, wherein assembling said first tack comprises attaching a head to a shaft of said tack.

30 40. A method according to any of claims 37-38, wherein assembling said first tack comprises attaching at least one fin to a shaft of said tack.

41. A method according to any of claims 30-40, wherein mounting said sling on said tack comprises piercing said sling by said tack.

42. A method according to any of claims 30-40, wherein mounting said sling on said tack comprises inserting said tack into a hole in said sling.

5 43. A method according to any of claims 30-42, comprising inserting at least a part of said tacking device into a human vagina, after mounting said tack on the tacking device.

44. A kit, comprising:

10 a sling formed of bio-compatible material and having a length and mechanical properties suitable for bladder neck supporting; and

at least one tack, having a head and a shaft, wherein said head has an extent perpendicular to the shaft, which extent is substantially greater than a diameter of the shaft.

15 45. A kit according to claim 44, wherein said sling contains at least one pre-punched aperture.

46. A kit according to claim 44, wherein said sling contains at least two adjacent pre-punched apertures, for setting an effective sling size.

20 47. A kit according to any of claims 44-46, wherein at least one tack comprises at least two tacks.

48. A kit according to any of claims 44-47, wherein said sling is reinforced at least at its ends.

25

49. A kit, comprising:

a sling formed of bio-compatible material and having a length and mechanical properties suitable for bladder neck supporting; and

30 a clip adapted to hold said sling against a tacking head of at least a particular tacking or stapling device.

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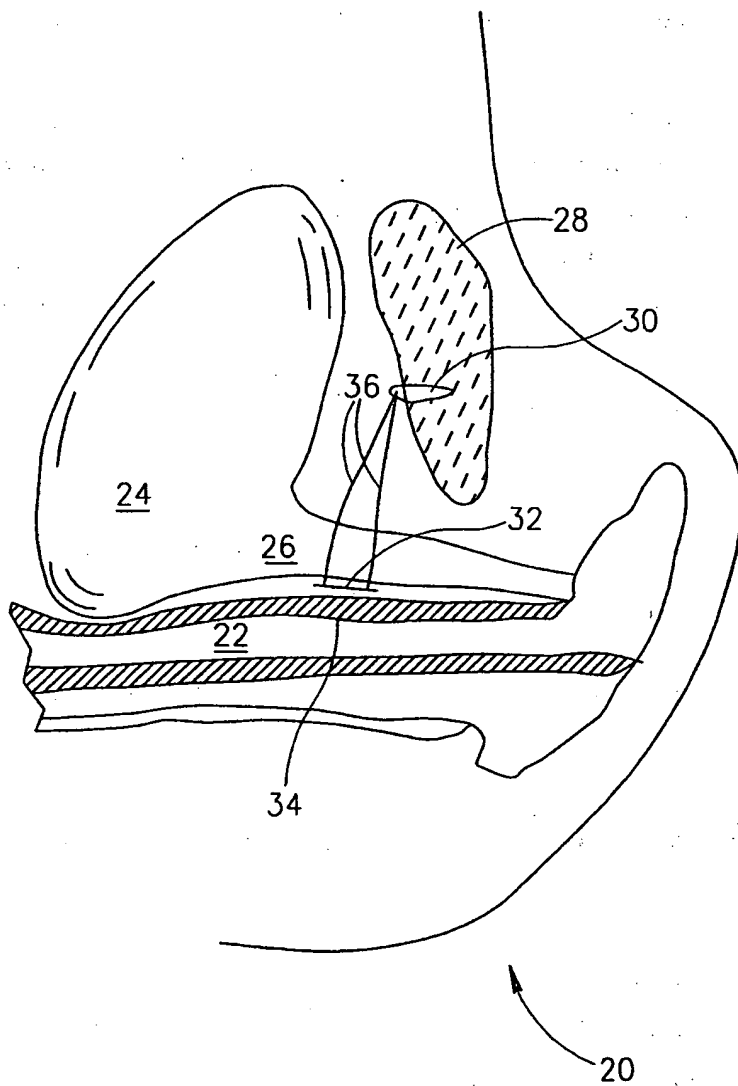


FIG.1
PRIOR ART

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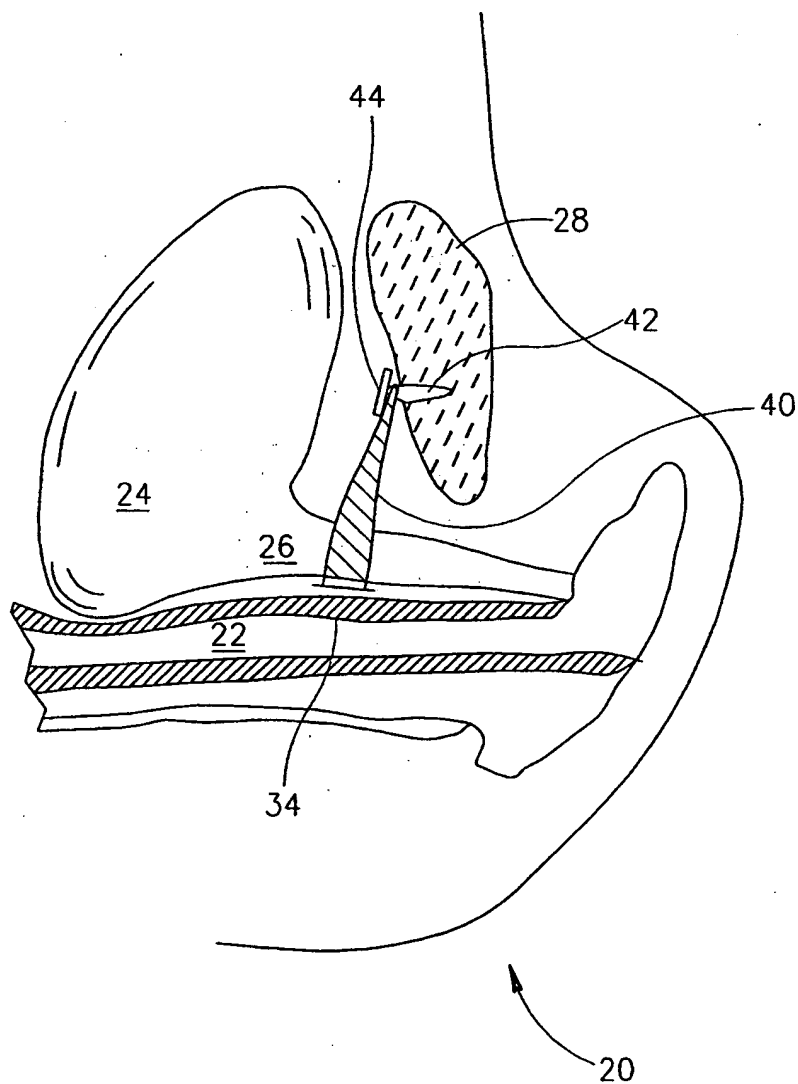


FIG.2

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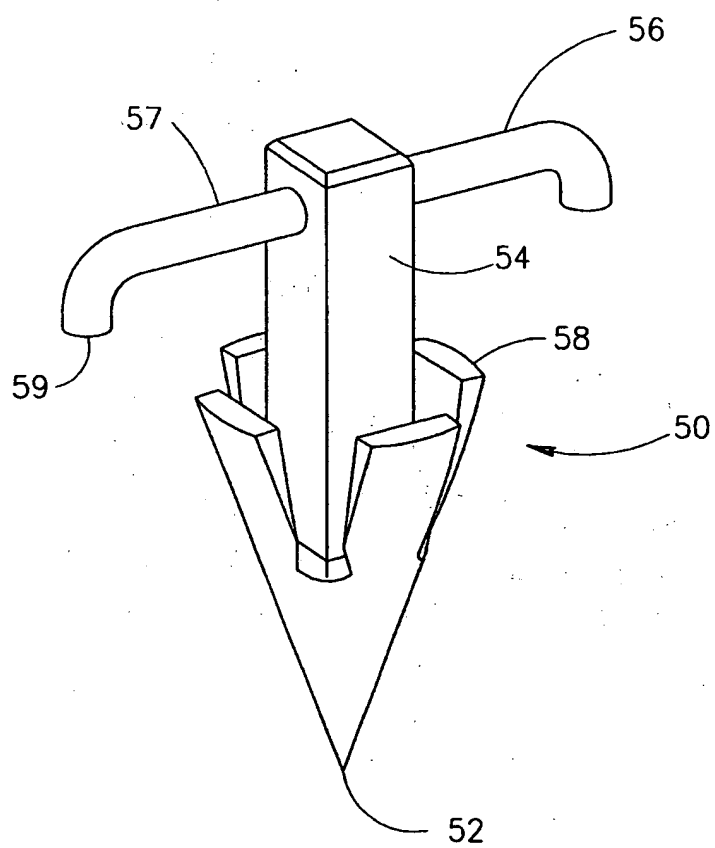


FIG. 3

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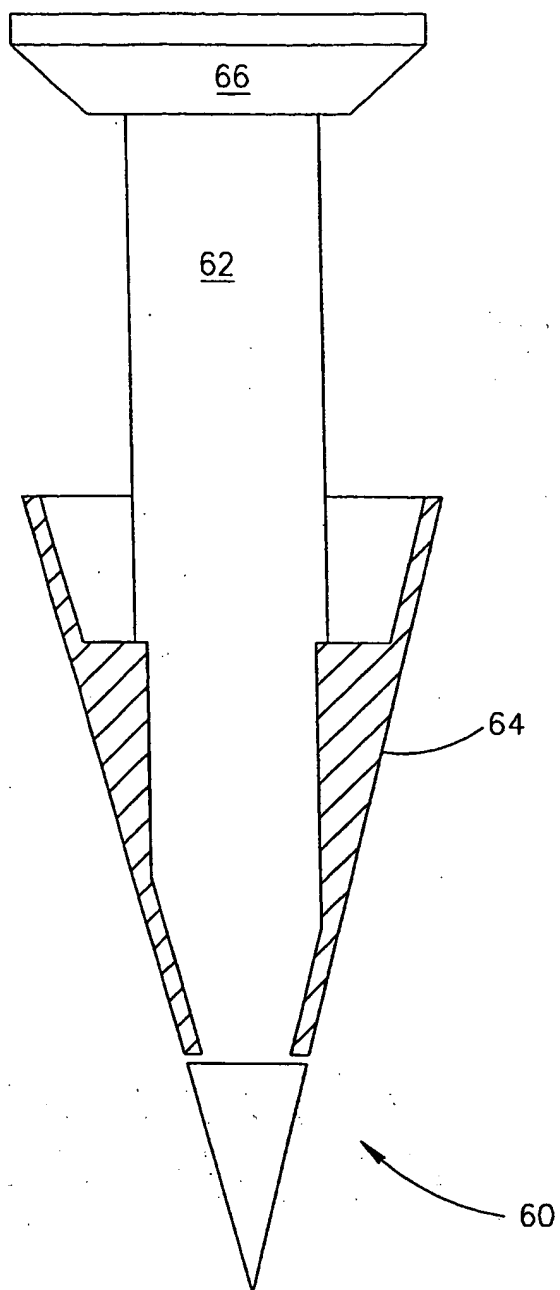


FIG. 4

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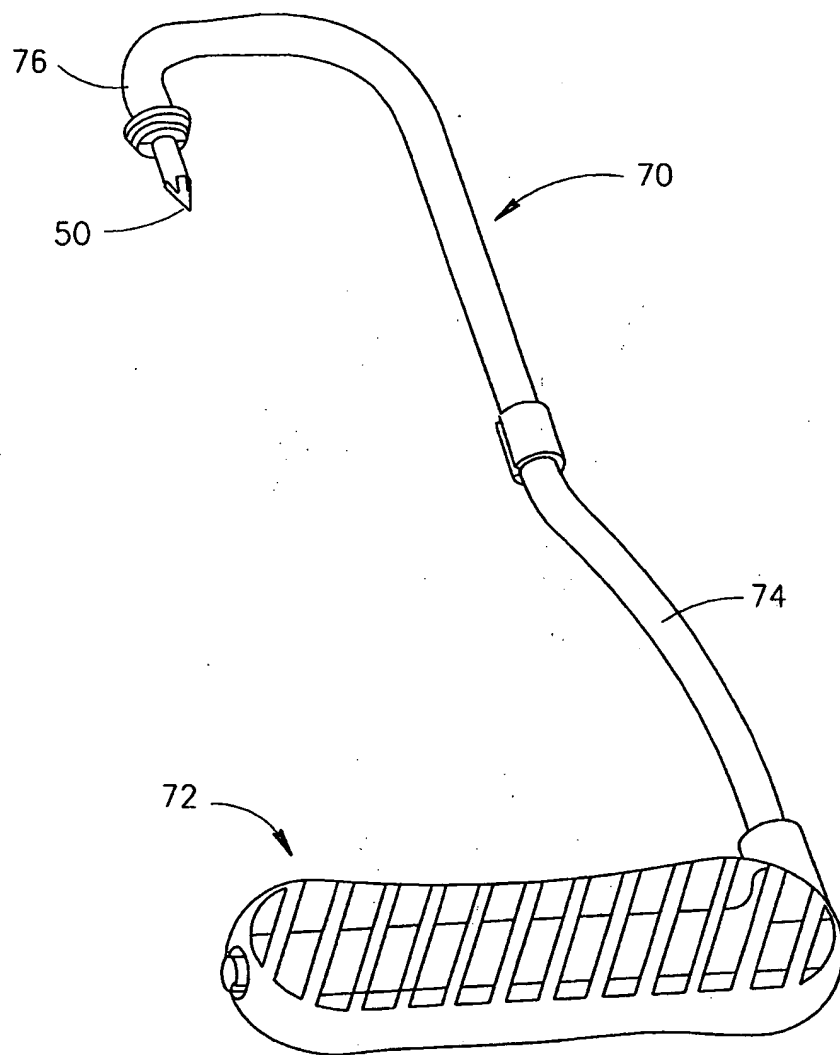


FIG. 5

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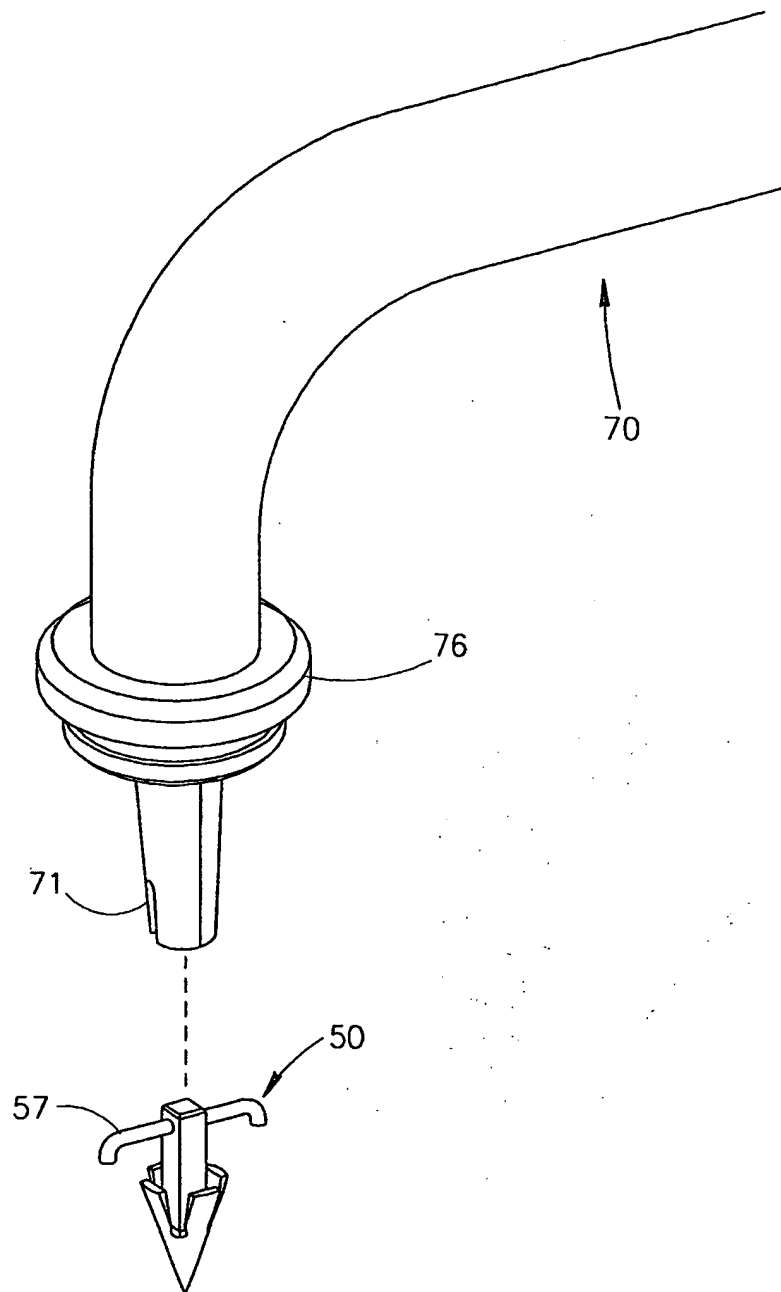


FIG.6

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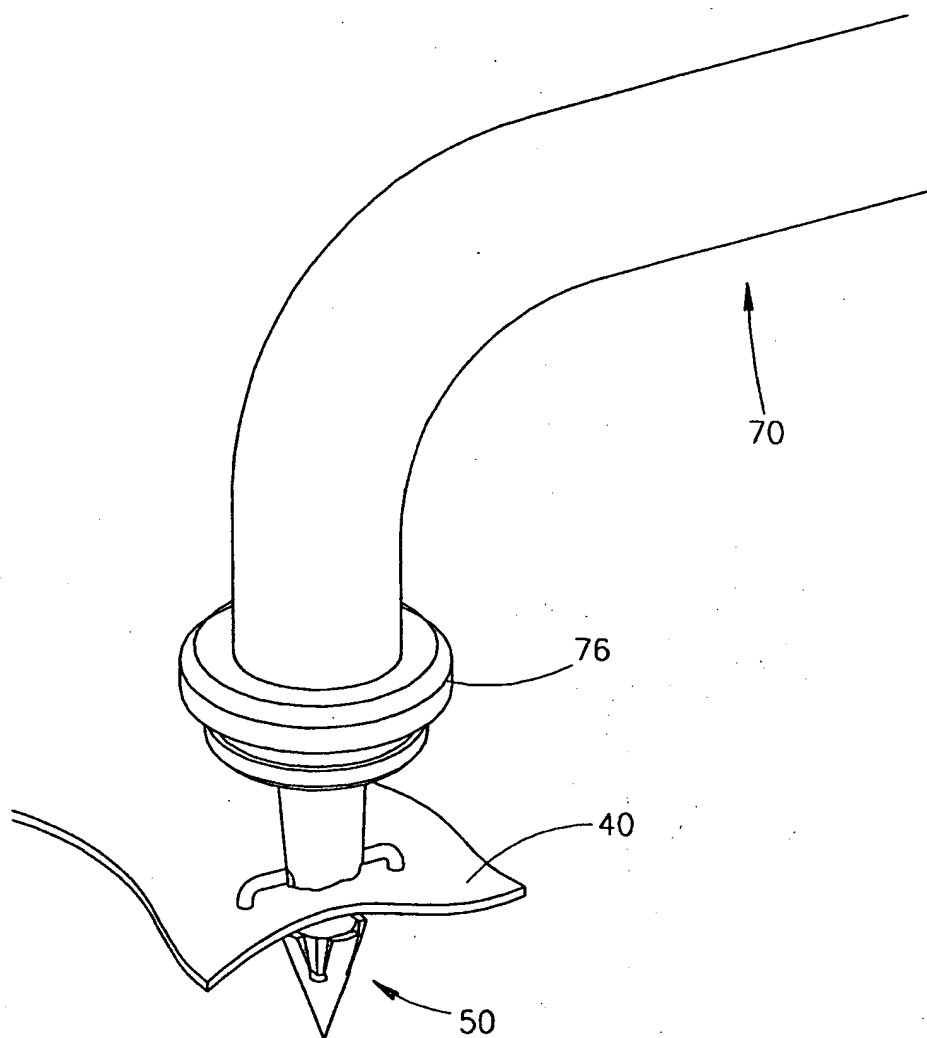


FIG. 7

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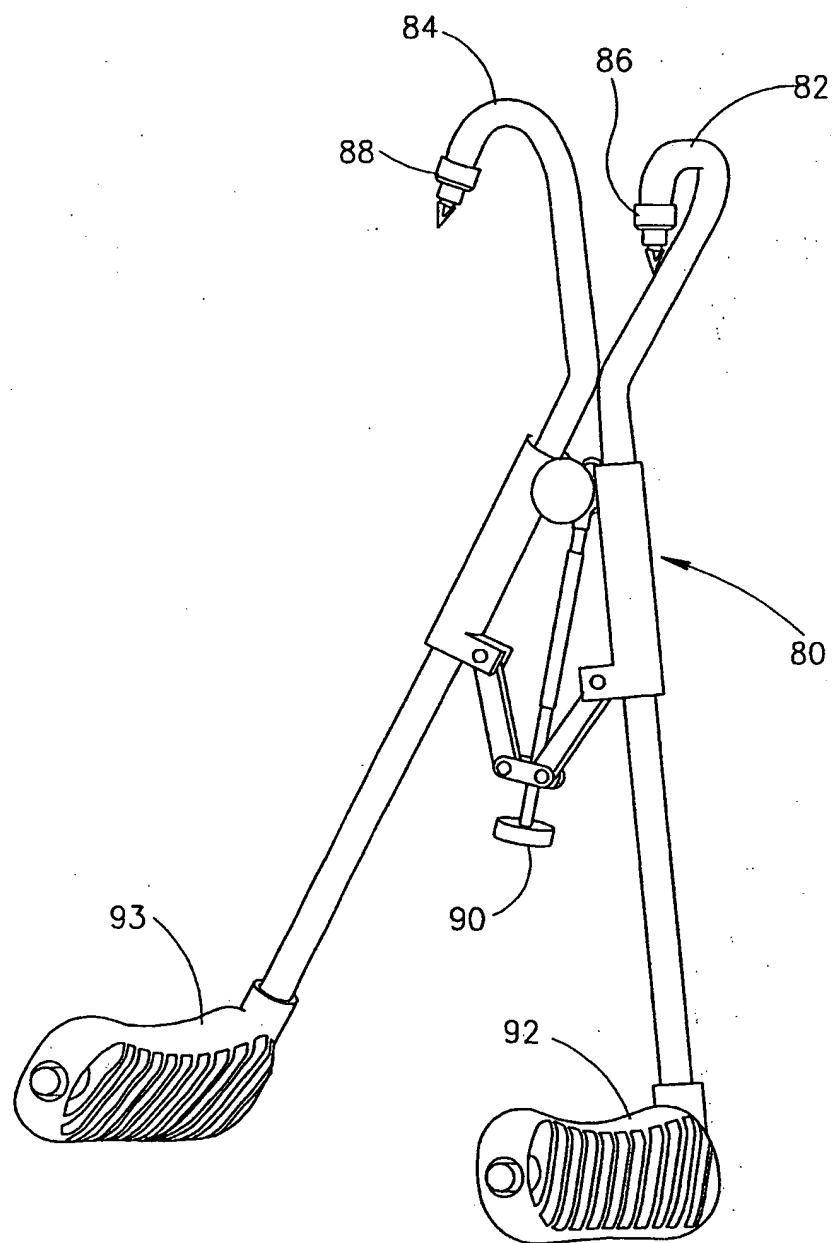


FIG. 8

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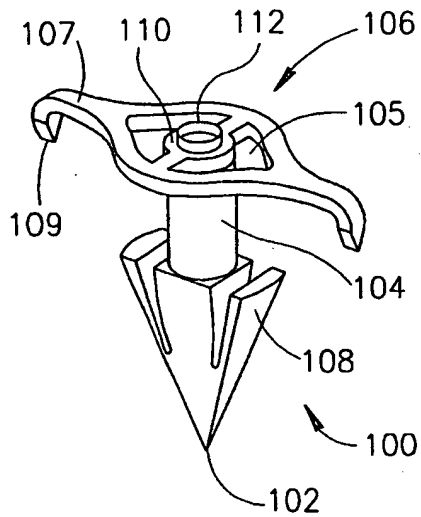


FIG. 9A

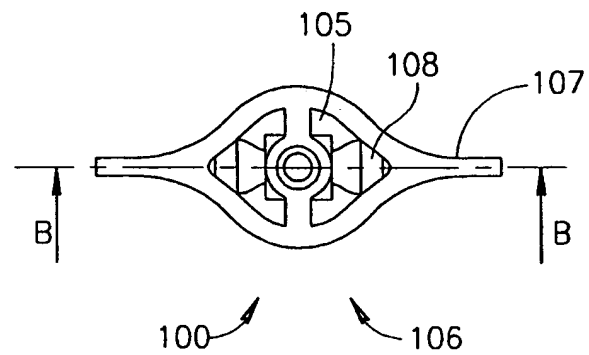


FIG. 9B

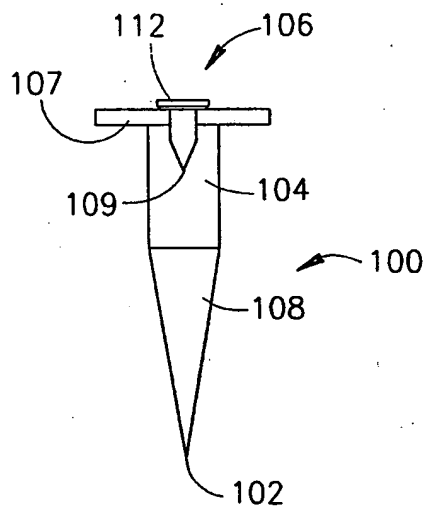


FIG. 9C

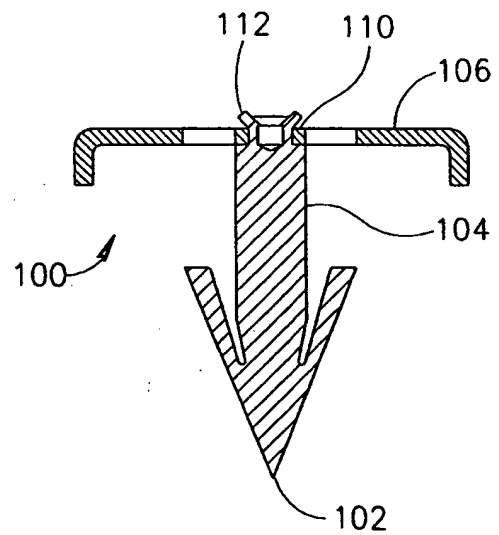


FIG. 9D

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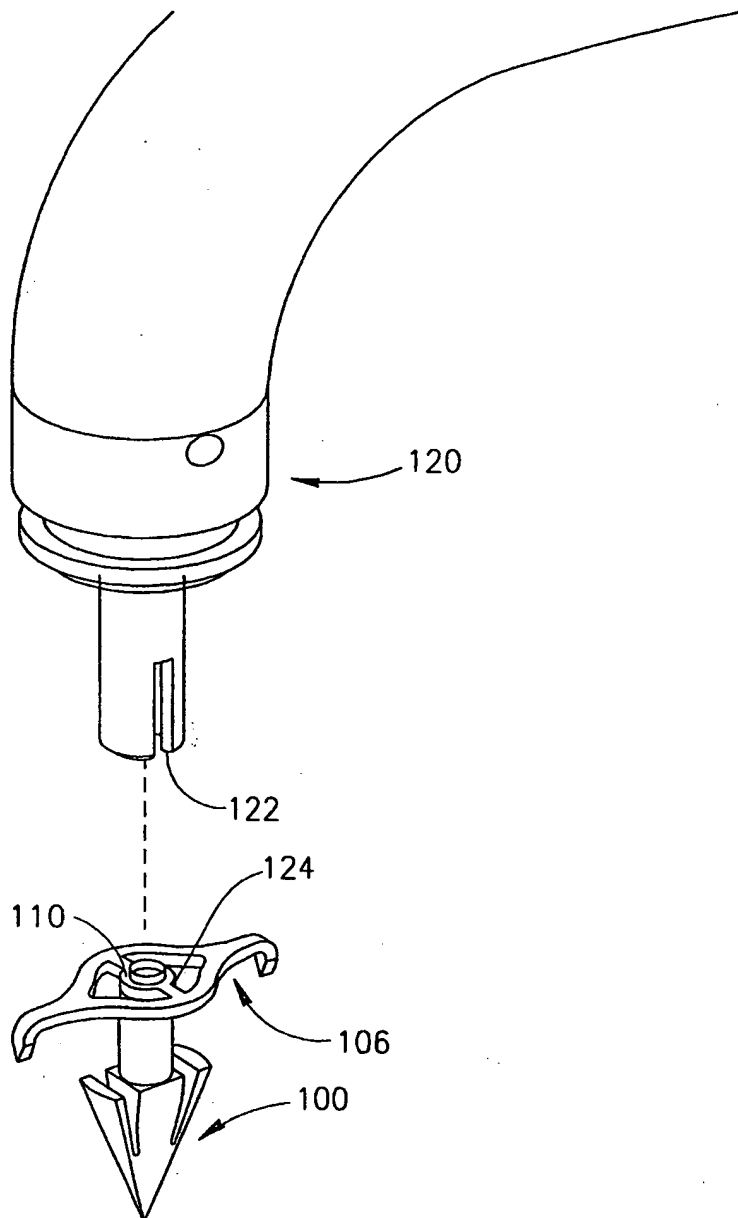


FIG.10

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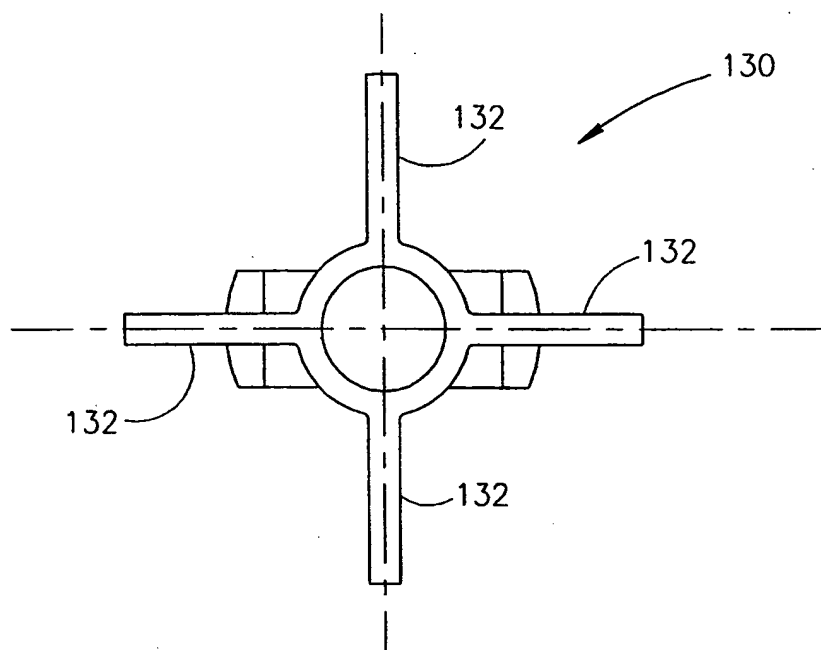


FIG. 11A

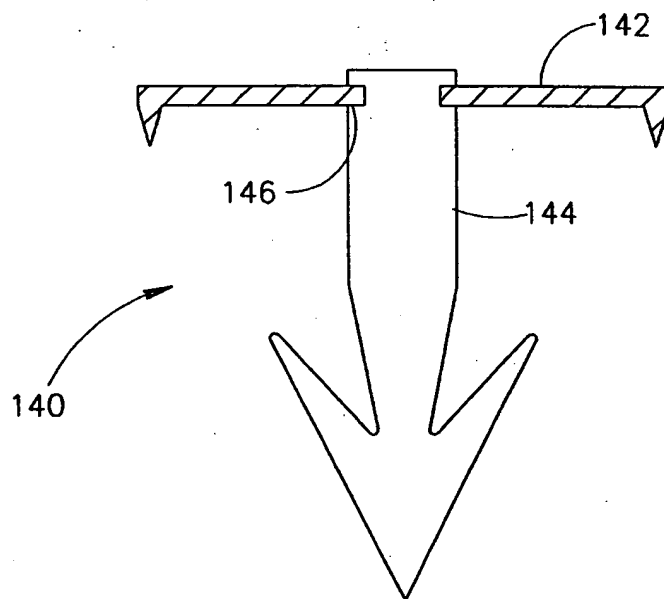


FIG. 11B

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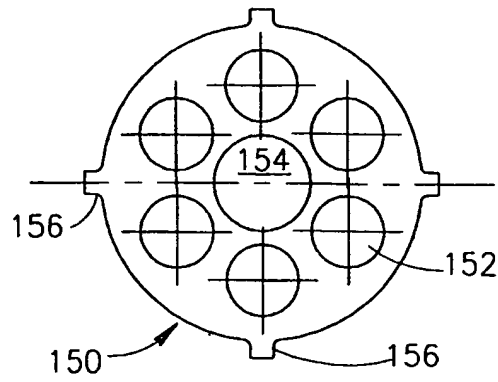


FIG. 12A

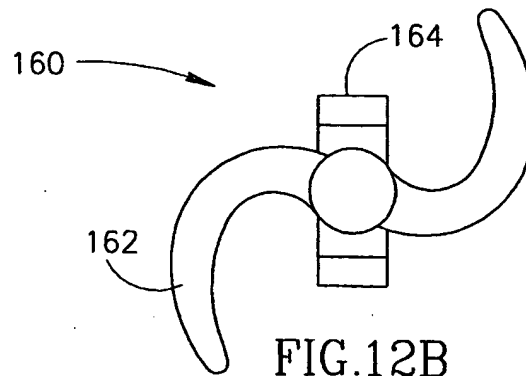


FIG. 12B

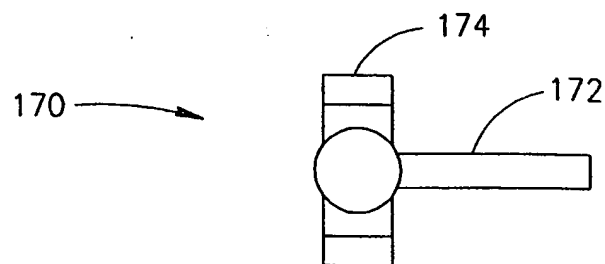


FIG. 12C

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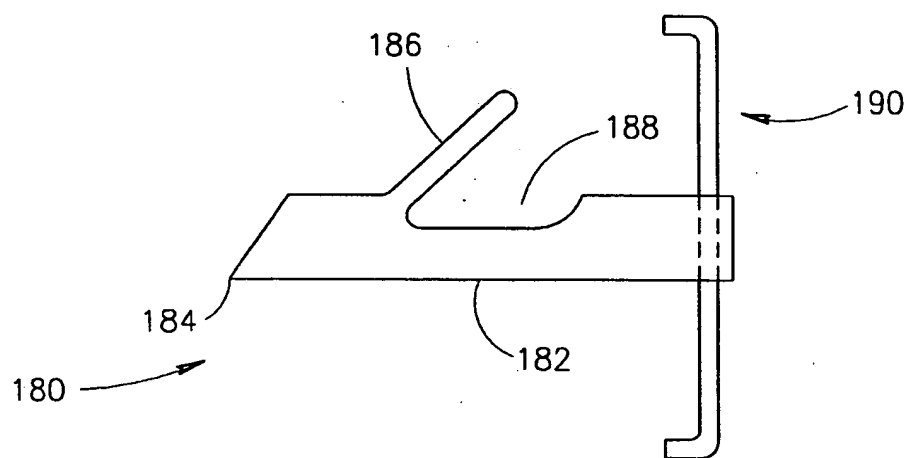


FIG.13A

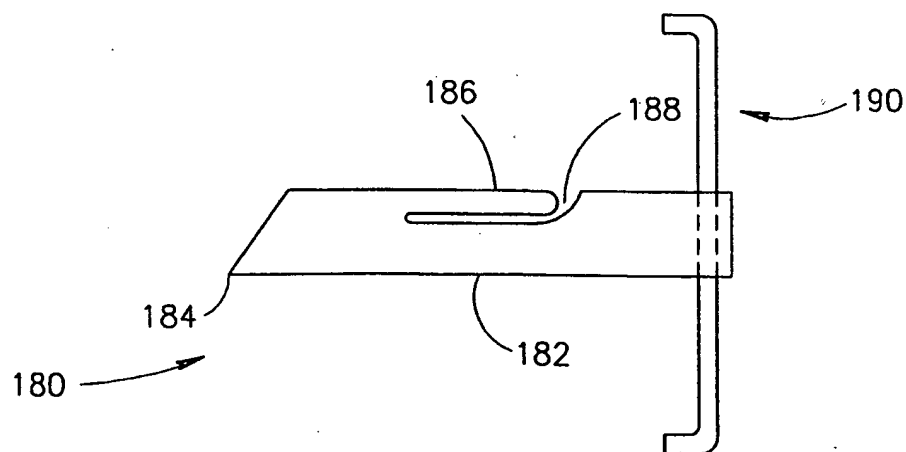


FIG.13B

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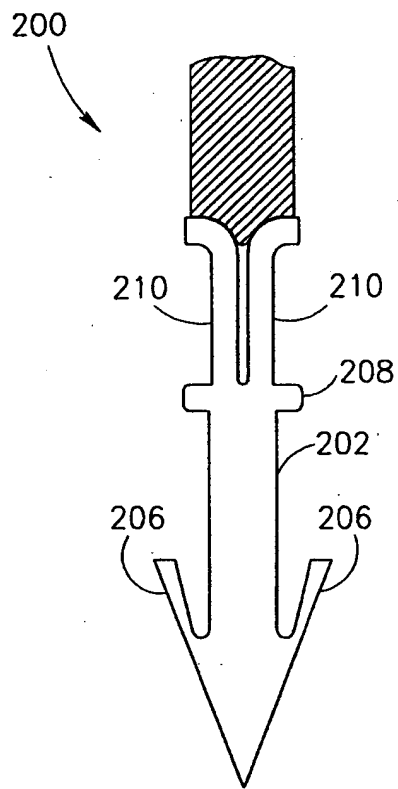


FIG.13C

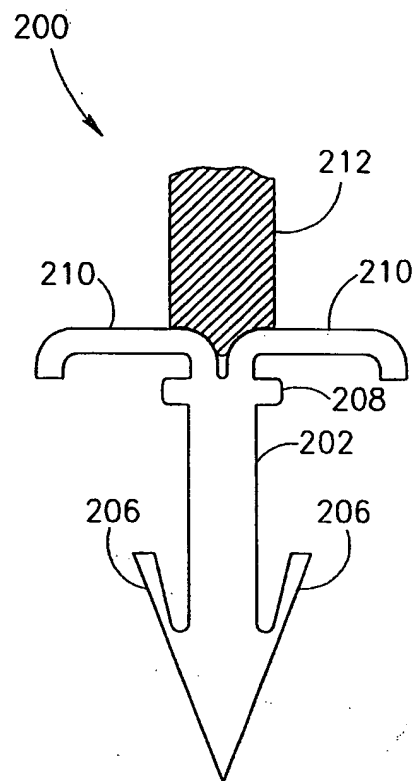


FIG.13D

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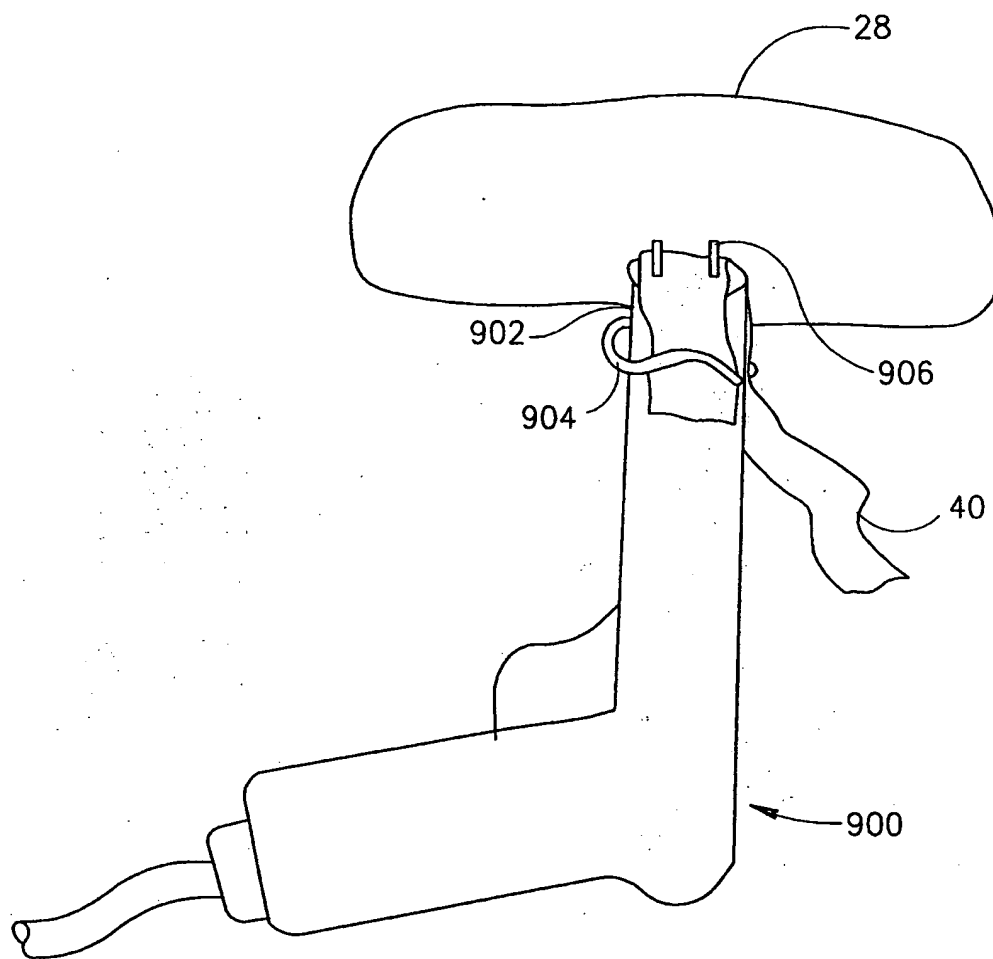


FIG. 14